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(57) Abstract

A medical guidewire (1) has a hinge (2, 14, 15, 20, 31) intermediate the ends thereof for in situ alignment of the guidewire in the lumen. The hinge means may be defined by portions (14, 15, 20, 31) of reduced cross section. The hinge may also be defined by a number of slots (32) in the guidewire (30).

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"IMPROVEMENTS IN MEDICAL GUIDEWIRES"

This invention relates to the delivery of medical devices.

Introduction

The invention is particularly concerned with filter elements for transcatheter embolic protection devices of the type described in our previously filed PCT Patent Application No. PCT/IE98/00093 the contents of which are incorporated herein by reference. One type of such embolic filter essentially comprises a filter body mounted on an associated collapsible support frame which can be collapsed against the guide wire by means of a catheter for deployment of the filter through a patient's vascular system. Upon retraction of the catheter the support frame and filter body expand outwardly from the guidewire across a blood vessel within which the filter is positioned to filter blood flowing through the blood vessel.

One of the major problems with the placing of devices such as embolic filter devices in situ is that the devices have limited freedom to move independently of the guidewire which is used to deploy the device. For example, the embolic filter described in PCT/IE98/0093 has freedom to move independently of the wire axially between distal and proximal stops. The filter can also be rotated. It would be advantageous to be able to move the guidewire off the central axis of the vessel through which it is moving without at the same time moving the central axis of the filter off-centre in the vessel. A relatively stiff guidewire is required to ensure delivery in certain tortuous areas. However the guidewire may drive the device off centre.

The present invention is directed towards an improved medical guidewire which further enhances the freedom of movement between the guidewire and a filter or other medical device.

Statements of Invention

According to the invention there is provided a medical guidewire comprising an elongate rod for leading through a body lumen of a patient, the guidewire having hinge means intermediate the ends thereof for in situ alignment of the guidewire in the lumen.

In a particularly preferred embodiment of the invention the hinge means is an integral hinge means.

In one arrangement the hinge means is defined by one or more portions of the guidewire of reduced cross section.

In one embodiment the hinge means is defined by slot means provided in the guidewire. The slot means preferably extends substantially circumferentially at least partially around the guidewire.

Usually there are a plurality of axially spaced-apart slots. Ideally at least some of the slots are circumferentially offset. Typically adjacent slots are circumferentially offset.

The invention also provides a guidewire of the invention having a medical device such as a stent or a collapsible embolic protection device mounted thereto.

The invention further provides a medical device incorporating a guidewire of the invention.

In one embodiment of the invention the medical device is an embolic protection device.

Brief Description of the Drawings

The invention will be more clearly understood by the following description of some of the embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which: -

Fig. 1 is partially sectioned elevational view an embolic protection device;

Fig. 2 is a schematic sectional elevational view of the embolic protection device of Fig. 1;

Fig. 3 is a detail sectional view of portion of the device of Fig. 1;

Fig. 4 is a longitudinal cross sectional view of the device of Fig. 1;

Fig. 5 is a cross sectional view of a distal end of the device of Fig. 1;

Fig. 6 is a view on the line A-A in Fig. 5;

Fig. 7 is a perspective view of a filter body of the device of Figs. 1 to 6;

Fig. 8 is a side elevational view of the filter body of Fig. 7;

Fig. 9 is a view on a proximal end of the filter body;

Fig. 10 is a perspective view of a support frame of the device of Figs. 1 to 6;

Fig. 11 is a side elevational view of the support frame;

Fig. 12 is a perspective view illustrating the manufacture of the support frame;

Fig. 13 is a view of the support frame and filter element assembly;

Fig. 14 is a schematic side view of a guidewire and transcatheter embolic protection device according to the invention;

Fig. 15 is a perspective view of a distal end of a device of the invention;

Fig. 16 is a perspective view of a detail of a device of the invention;

Fig. 17 is a perspective view of portion of another guidewire according to the invention;

Fig. 18 is a plan view of the guidewire portion of Fig. 17;

Figs. 19 and 20 are plan views of further guidewire portions; and

Fig. 21 is a schematic view of another guidewire of the invention.

Referring to Figs. 1 to 13 there is illustrated an embolic protection device as described in our co-pending Application PCT/IE98/00093 indicated generally by the reference number 100. The device 100 has a guidewire 101 with a proximal end 102 and a distal end 103. A tubular sleeve 104 is slidably mounted on the guidewire 101. A collapsible filter 105 is mounted on the sleeve 104, the filter 105 being movable between a collapsed stored position against the sleeve 104 and an expanded position as shown in the drawings extended outwardly of the sleeve 104 for deployment in a blood vessel.

The sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101.

The filter 105 comprises a filter body 110 mounted over a collapsible support frame 111. The filter body 110 is mounted to the sleeve 104 at each end, the body 110 being rigidly attached to a proximal end 112 of the sleeve 104 and the body 110 being attached to a collar 115 which is slidable along a distal end 114 of the sleeve 104. Thus the distal end of the body 110 is longitudinally slidable along the sleeve 104. The support frame 111 is also fixed at the proximal end 112 of the sleeve 104. A distal end 116 of the support frame 111 is not attached to the sleeve 104 and is thus also free to move longitudinally along the sleeve 104 to facilitate collapsing the support frame 111 against the sleeve 104. The support frame 111 is such that it is naturally expanded as shown in the drawings and can be collapsed inwardly against the sleeve 104 for loading in a catheter 118 or the like.

The filter body 105 has large proximal inlet openings 117 and small distal outlet openings 119. The proximal inlet openings 117 allow blood and embolic material to enter the filter body, however, the distal outlet openings 119 allow through passage of blood but retain undesired embolic material within the filter body.

An olive guide 120 is mounted at a distal end of the sleeve 104 and has a cylindrical central portion 121 with tapered ends 122, 123. The distal end 122 may be an arrowhead configuration for smooth transition between the catheter and olive surfaces. The support frame 111 is shaped to provide a circumferential groove 125 in the filter body 110. If the filter is too large for a vessel, the body may crease and this groove 125 ensures any crease does not propagate along the filter.

Enlarged openings are provided at a proximal end of the filter body 110 to allow ingress of blood and embolic material into an interior of the body 110.

In use, the filter 105 is mounted in a collapsed state within a distal end of the catheter 118 and delivered to a deployment site. When the filter is correctly positioned the catheter 118 is retracted allowing the support frame 111 to expand

expanding the filter body 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the filter body 110. The blood will pass through the net wall, however, the openings or pores in the net are sized so as to retain the embolic material. After use the catheter is delivered along the guidewire 101 and slid over the filter 105 engaging the proximal inlet end 112 first to close the openings and then gradually collapsing the filter body against the sleeve 104 as the catheter 118 advances over the filter 105. Once the filter 105 is fully loaded in the catheter 118, it can then be withdrawn.

It will be noted that a proximal end of the filter is fixed and a distal end of the filter is longitudinally movable along the sleeve to facilitate collapsing of the filter body.

Further, the catheter engages the proximal end of the filter body first thus closing the filter body inlet and preventing escape of embolic material from the filter body as the filter body is being collapsed.

The outer filter body 110 is preferably of a resilient biocompatible elastomeric material. The material may be a polyurethane based material. There are a series of commercially available polyurethane materials that may be suitable. These are typically based on polyether or polycarbonate or silicone macroglycols together with diisocyanate and a diol or diamine or alkanolamine or water chain extender. Examples of these are described in EP-A-461,375 and US 5,621, 065. In addition, polyurethane elastomers manufactured from polycarbonate polyols as described in US 5,254,622 (Szycher) are also suitable.

The filter material may also be a biostable polycarbonate urethane article an example of which may be prepared by reaction of an isocyanate, a chain extender and a polycarbonate copolymer polyol of alkyl carbonates. This material is described in our co-pending PCT Application No. IE98/00091, filed November 9,

1998, the entire contents of which are incorporated herein by reference. The filter material may be manufactured from a block and cut into a desired shape. However the filter is preferably formed by dipping a rod of desired geometry into a solution of the material which coats the rod. The rod is then dissolved. The final geometry of the filter may be determined in the dipping step or the final geometry may be achieved in a finishing operation. Typically the finishing operations involve processes such as mechanical machining operations, laser machining or chemical machining.

The filter body is of hollow construction and is formed as described above by dipping a rod in a solution of polymeric material to coat the rod. The rod is then dissolved, leaving a hollow body polymeric material. The rod may be of an acrylic material which is dissolved by a suitable solvent such as acetone.

The polymeric body thus formed is machined to the shape illustrated in Figs. 1 to 13. The final machined filter body comprises an inlet or proximal portion 210 with a proximal neck 212, and outlet or distal portion 213 with a distal neck 214, and an intermediate portion 215 between the proximal and distal portions.

The inlet holes 117 are provided in the proximal portion 210 which allow the blood and embolic material to flow into the filter body. In this case the proximal portion 210 is of generally conical shape to maximise the hole size.

The intermediate portion 215 is also hollow and in this case is of generally cylindrical construction. This is important in ensuring more than simple point contact with the surrounding blood vessel. The cylindrical structure allows the filter body to come into soft contact with the blood vessel to avoid damaging the vessel wall.

The intermediate portion 215 is provided with a radial stiffening means, in this case in the form of a radial strengthening ring or rim 220. The ring 220 provides

localised stiffening of the filter body without stiffening the material in contact with the vessel. Such an arrangement provides appropriate structural strength so that line apposition of the filter body to the vessel wall is achieved. It is expected that other geometrics of stiffening means will achieve a similar result.

The tubular intermediate portion 215 is also important in maintaining the stability of the filter body in situ to retain captured emboli and to ensure that flow around the filter is minimised. For optimum stability we have found that the ratio of the axial length of the intermediate portion 215 of the filter body to the diameter of the intermediate portion 215 is preferably at least 0.5 and ideally greater than 1.0.

The collapsible support frame 111 has four foldable arms 290 which are collapsed for deployment and upon release extend outwardly to expand the filter body 110.

The support frame 111 can be manufactured from a range of metallic or polymeric components such as a shape memory alloy like nitinol or a shape memory polymer or a shaped stainless steel or metal with similar properties that will recover from the deformation sufficiently to cause the filter body 110 to open.

The support frame may be formed as illustrated in Fig. 12 by machining slots in a tube 291 of shape memory alloy such as nitinol. On machining, the unslotted distal end of the tube forms a distal collar 293 and the unslotted proximal end of the tube forms a proximal collar 294. In use, the distal collar 293 is slidably moveable along the tubular sleeve 104 which in turn is slidably mounted on the guidewire 101 for deployment and retrieval. The proximal collar 294 is fixed relative to the tubular sleeve 104.

To load the filter the sub assembly of the support frame and filter body is pulled back into the catheter 118 to engage the distal stop 107. The support arms 290 are hinged inwardly and the distal collar 293 moves forward along the tubular sleeve 104. As the support arms 290 enter the catheter 118 the filter body 110 stretches

as the filter body collar 115 slides along the tubular sleeve 104 proximal to the olive 120. On deployment, the catheter 118 is retracted proximally along the guidewire 101 initially bringing the collapsed filter assembly with it until it engages the proximal stop 106. The catheter sleeve then begins to pull off the filter freeing the support arms 290 to expand and the filter body apposes the vessel wall.

For retrieval, a retrieval catheter is introduced by sliding it over the guidewire 101 until it is positioned at the proximal end of the filter body and support frame. Pulling the guidewire 101 will initially engage the distal stop 107 with the filter element and begin to pull it into the retrieval catheter. The initial travel into the delivery catheter acts to close the proximal openings of the filter element, thus entrapping the embolic load. As the filter continues to be pulled back the filter body and the support frame are enveloped in the retrieval catheter. The collapsed filter may then be removed from the patient.

The guidewire can incorporate a hinge joint. Alternatively the guidewire can incorporate a hinge joint with the proximal portion of the guidewire being of a larger diameter and having a greater stiffness than the distal portion.

Referring to Fig. 14 there is illustrated a guidewire indicated generally by the reference numeral 1 having a hinge 2 adjacent the distal end thereof. The hinge 2 is positioned on the side of a medical device to be deployed remote from and before the proximal end of the medical device and the guidewire tip 4. The arrangement allows the guidewire to move in such a way as to ensure that the medical device is maintained central. The medical device may be a filter 3 as illustrated or any item to be moved through a body lumen.

Referring now to Fig. 15, there is illustrated a guidewire indicated generally by the reference numeral 10 having a proximal portion 11 and a distal portion 12 terminating in a tip 13 on the distal portion of which is mounted a medical device,

in this case a filter 15. The guidewire portion 12 is of a smaller diameter than the guidewire portion 11 and is connected thereto by spaced-apart hinge points 14 and 15 respectively. The filter 15 is loaded over the guidewire portion 12 and is held in place between two stops 17, 18.

Referring to Fig. 16 there is illustrated another construction of hinge formed by a thin section 20, for example, of one third the diameter of a proximal portion 21. The thin section 20 can be connected to a distal portion 22 of smaller diameter than that of the proximal portion 21, or can be connected to a distal portion of the same diameter.

Referring to Figs. 17 and 18 there is illustrated portion of another guidewire 30 according to the invention. In this case a guidewire hinge 31 is formed by a number of radially extending slots 32 in the wire 30. The slots are spaced-apart along portion of the wire 30 in any desired pattern to achieve the required hinging effect. One particular configuration is illustrated in Figs. 17 and 18. However, the slots may be offset in any desired pattern as illustrated in Figs. 19 and 20 and by various interrupted lines in Fig. 21.

The invention is not limited to the embodiments hereinbefore described which may be varied in both construction and detail.

Claims

1. A medical guidewire comprising an elongate rod for leading through a body lumen of a patient, the guidewire having hinge means intermediate the ends thereof for in situ alignment of the guidewire in the lumen.

2. A guidewire as claimed in claim 1 wherein the hinge means is an integral hinge means.

3. A guidewire as claimed in claim 2 wherein the hinge means is defined by one or more portions of the guidewire of reduced cross section.

4. A medical guidewire as claimed in any of claims 1 to 3 wherein a pair of spaced-apart hinges are provided in the guidewire proximally of the medical device.

5. A medical guidewire as claimed in any preceding claim wherein the guidewire has a stepped configuration, a distal portion of the guidewire being of a reduced cross-sectional area in comparison to a proximal portion of the guidewire.

6. A guidewire as claimed in claim 2 wherein the hinge means is defined by slot means provided in the guidewire.

7. A guidewire as claimed in claim 6 wherein the slot means extends substantially circumferentially at least partially around the guidewire.

8. A guidewire as claimed in claim 7 wherein there are a plurality of axially spaced-apart slots.

9. A guidewire as claimed in claim 8 wherein at least some of the slots are circumferentially offset.

10. A guidewire as claimed in claim 9 wherein adjacent slots are circumferentially offset.

11. A guidewire as claimed in any preceding claim having a medical device such as a stent or a collapsible embolic protection device mounted thereto.

12. A medical device incorporating a guidewire as claimed in any preceding claim.

13. A medical device as claimed in claim 10 wherein the device is an embolic protection device.

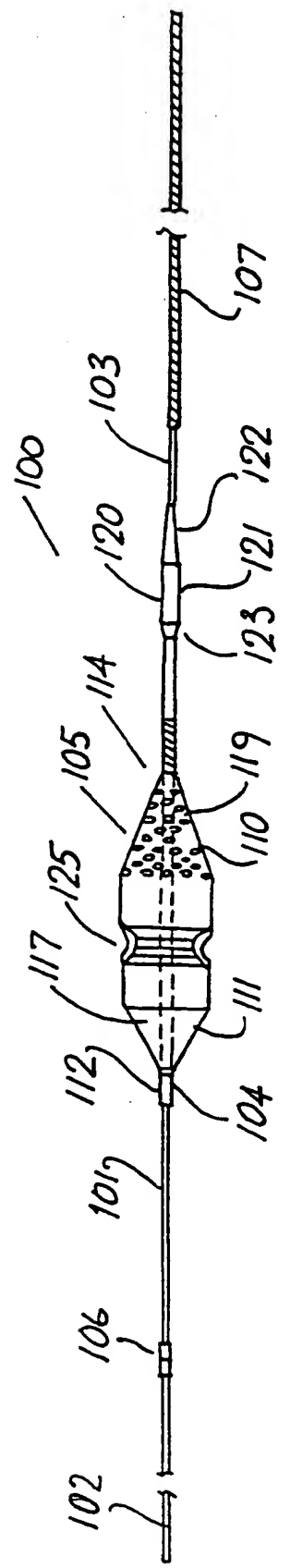
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Fig.1

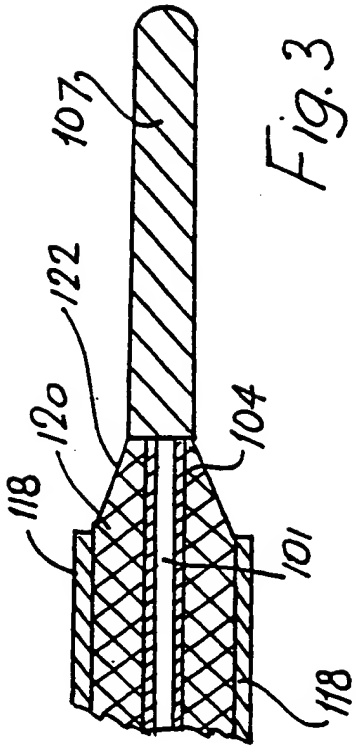
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Fig. 3

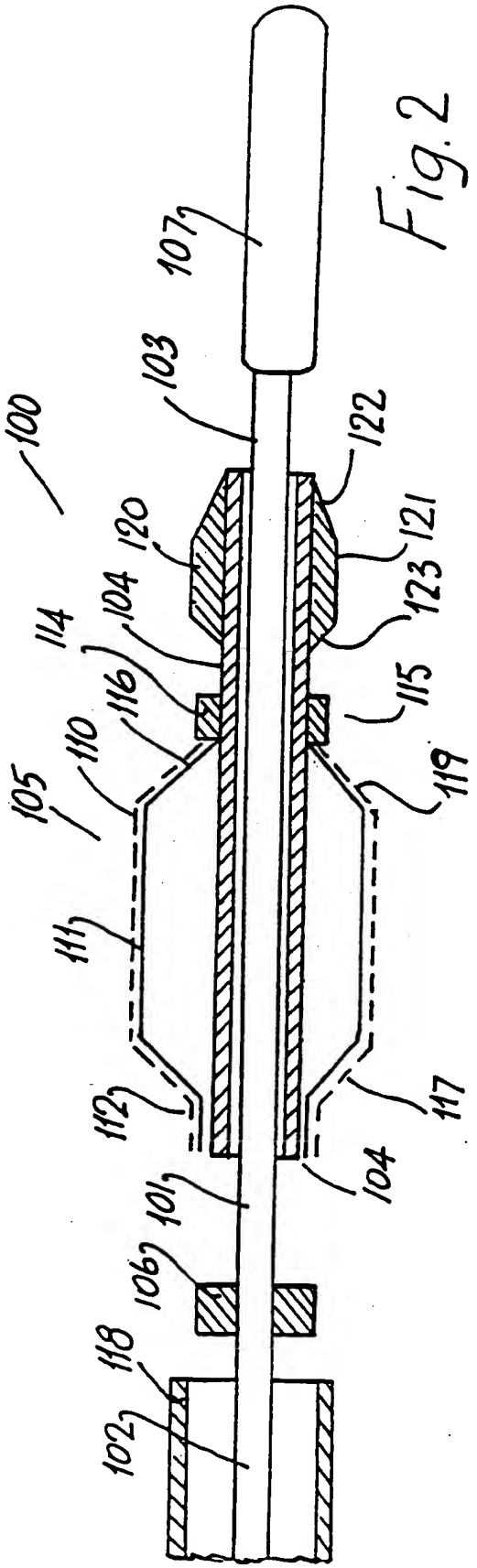
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Fig. 2

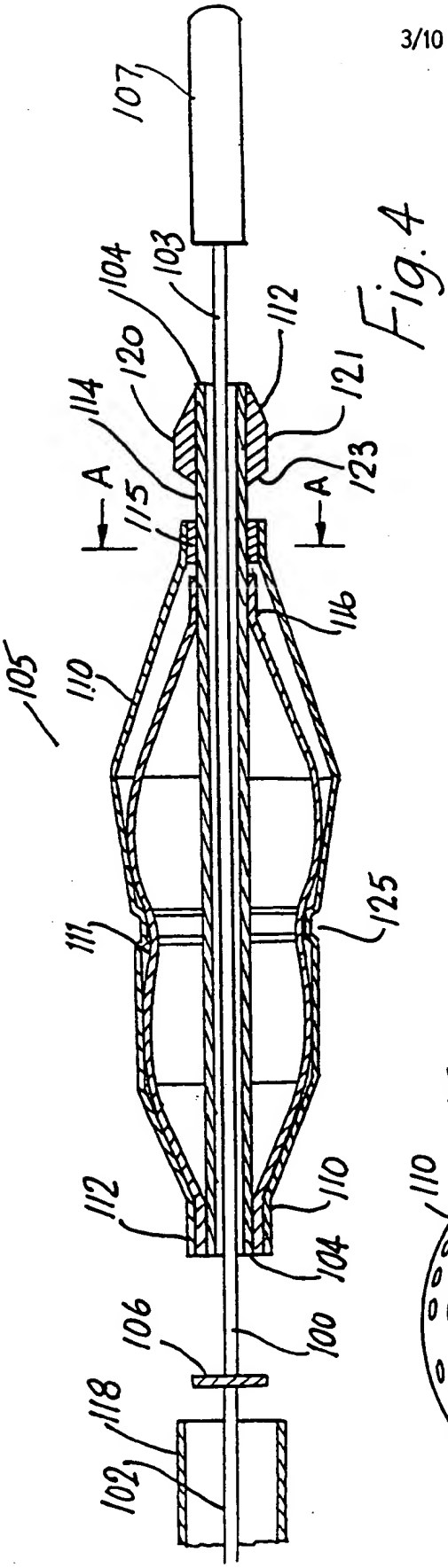

Fig. 4

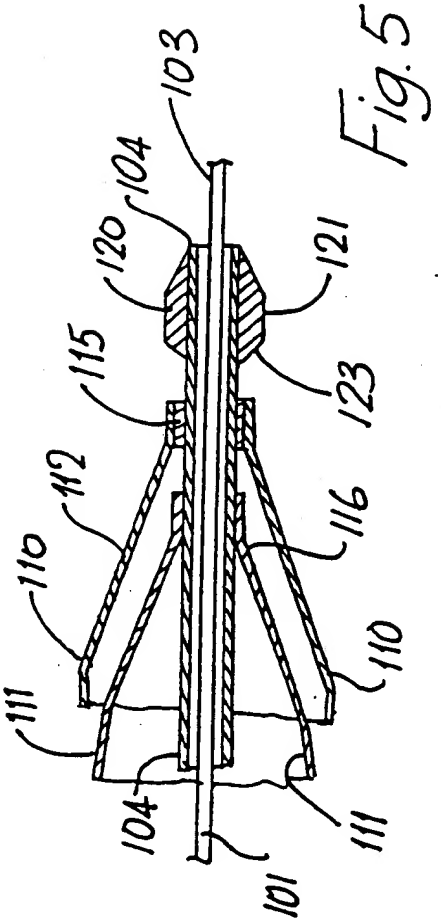

Fig. 5

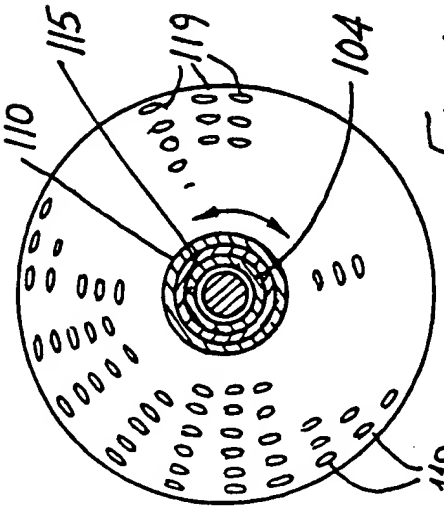

Fig. 6

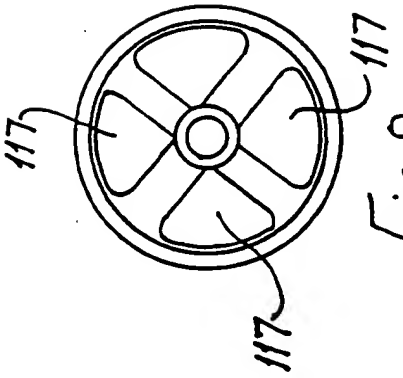

Fig. 9

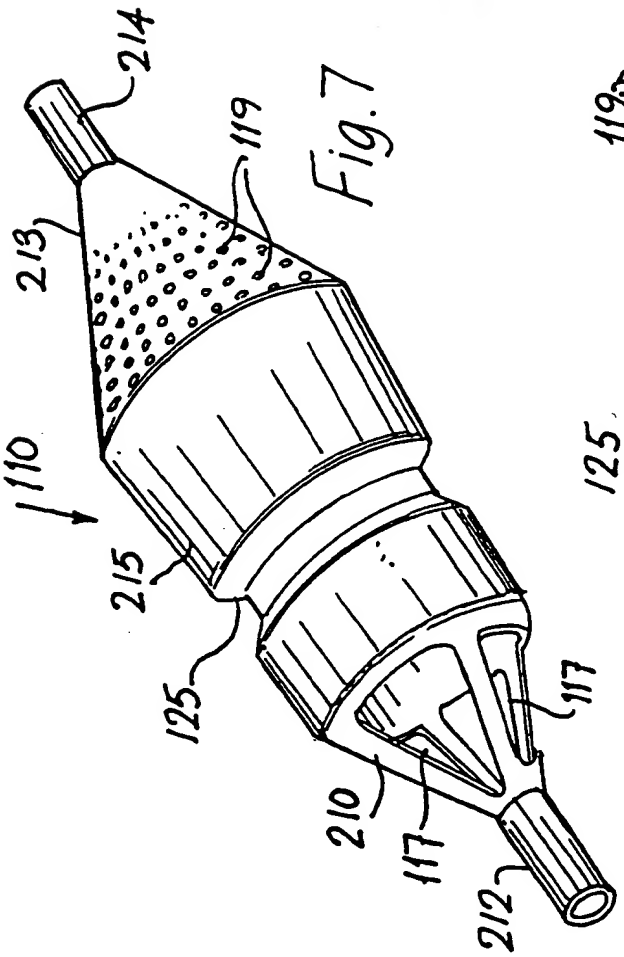

Fig. 7

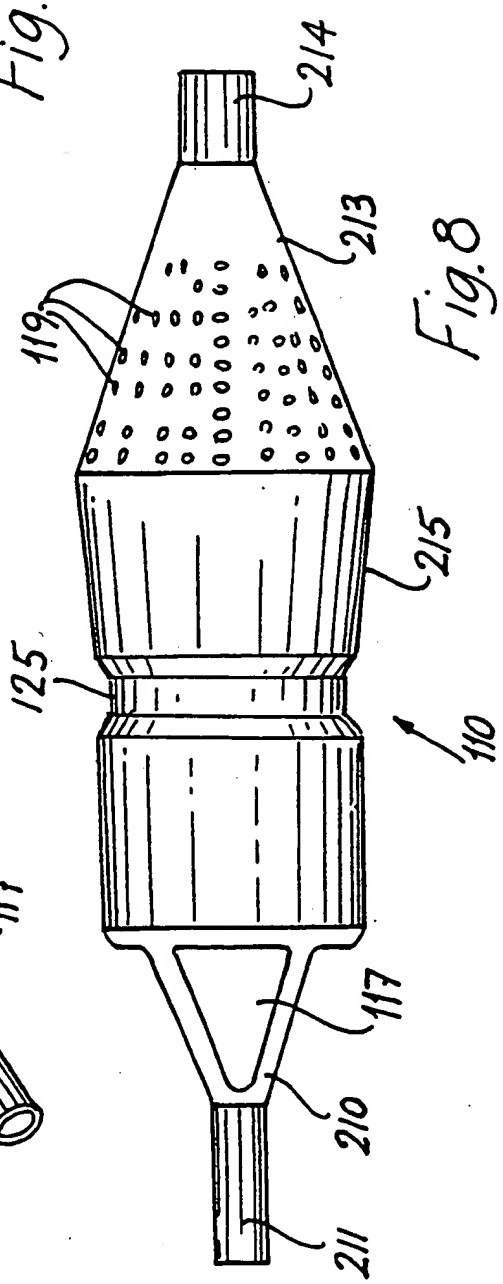

Fig. 8

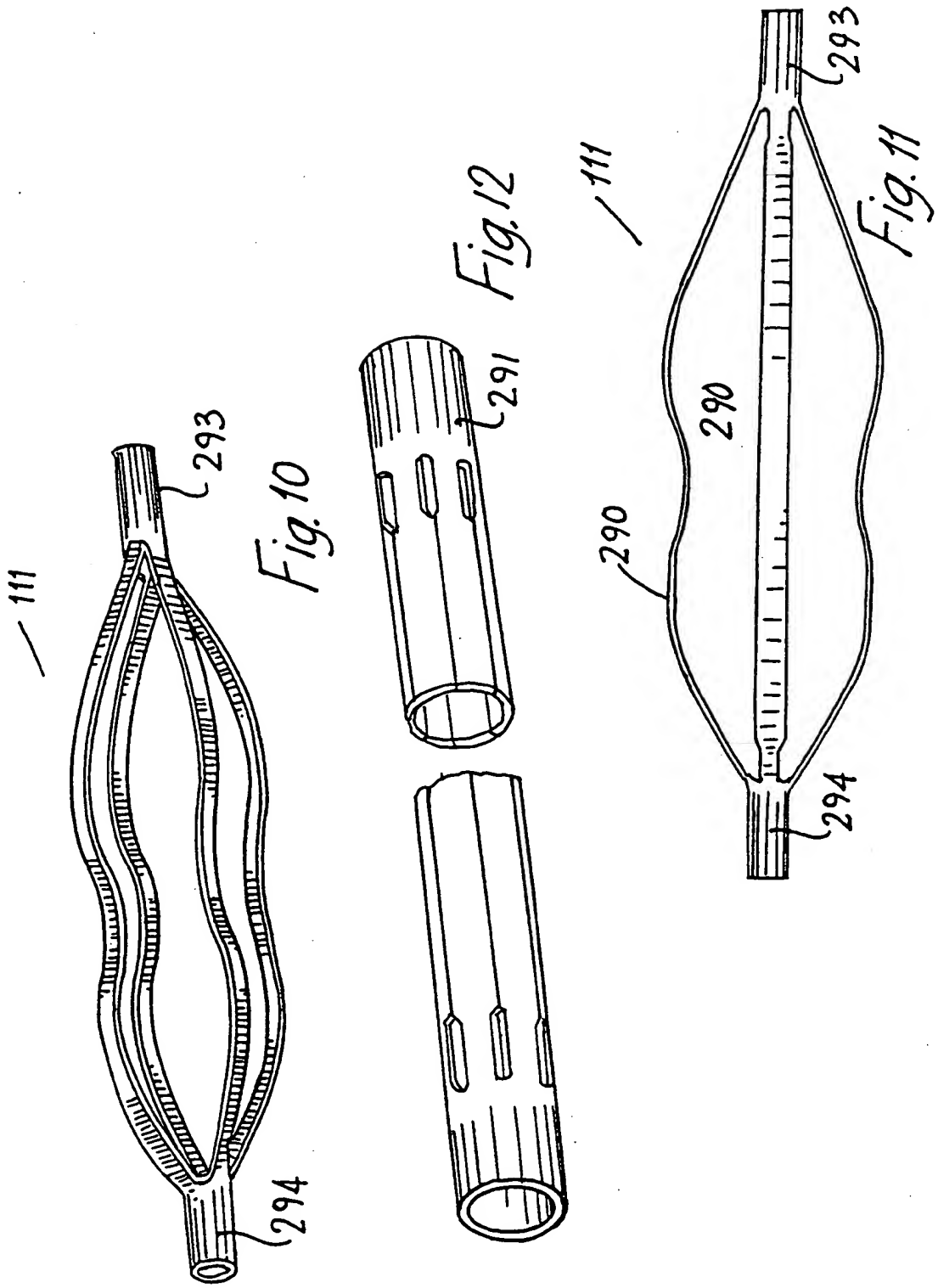

Fig. 10

Fig. 12

Fig. 11

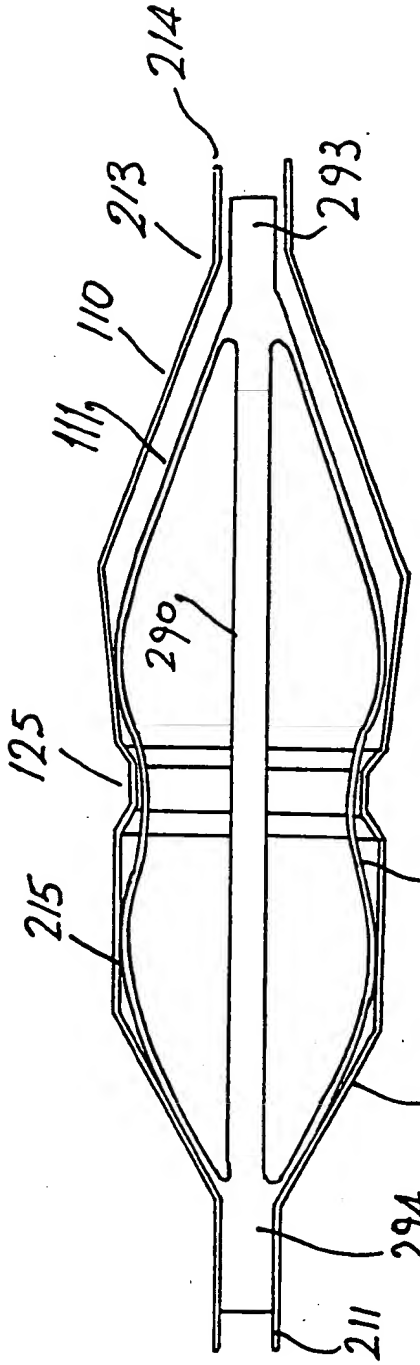

Fig. 13

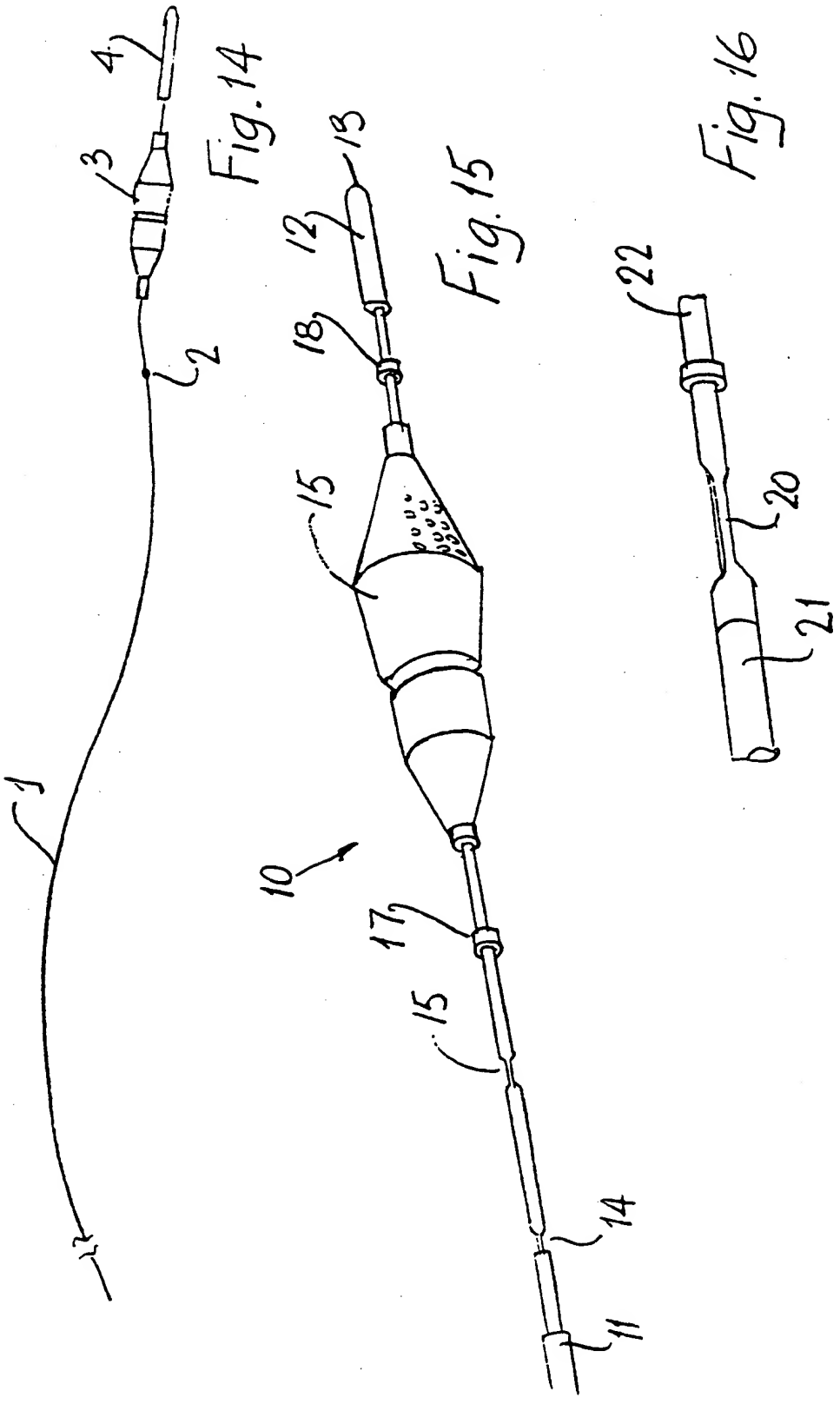
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Fig. 14
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Fig. 15
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Fig. 16

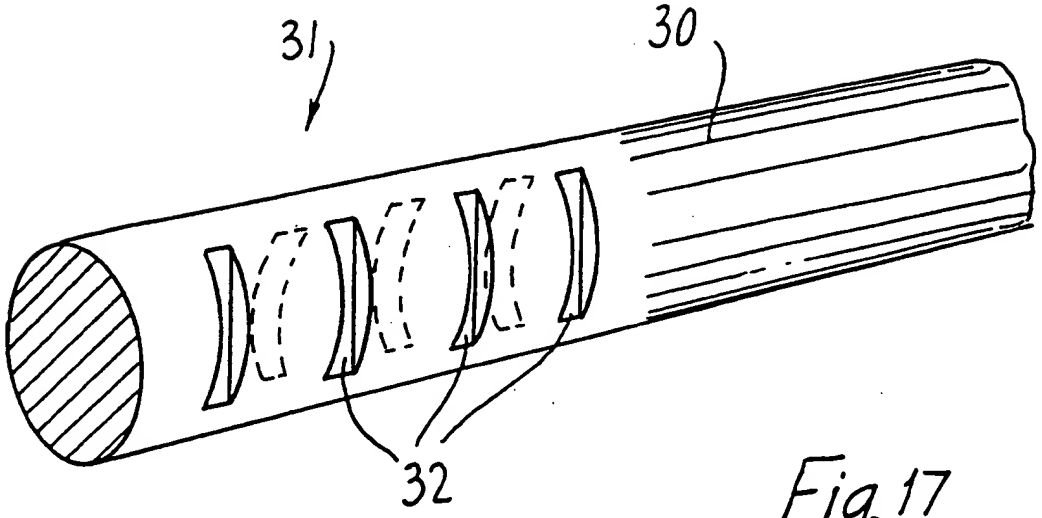

Fig. 17

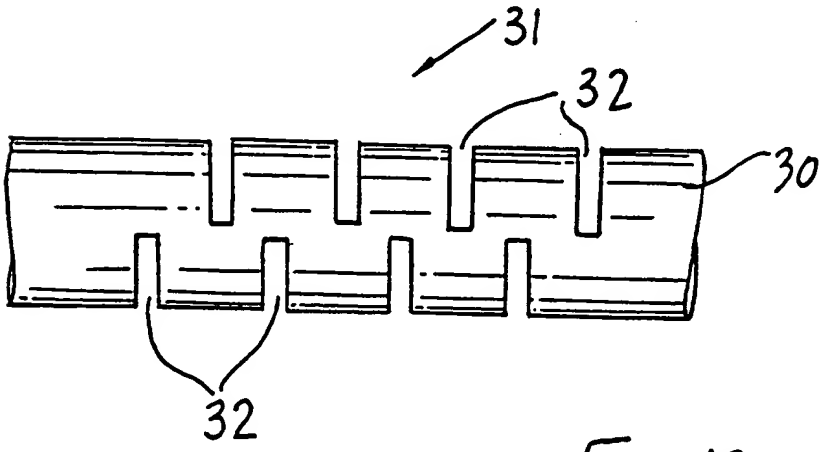

Fig. 18

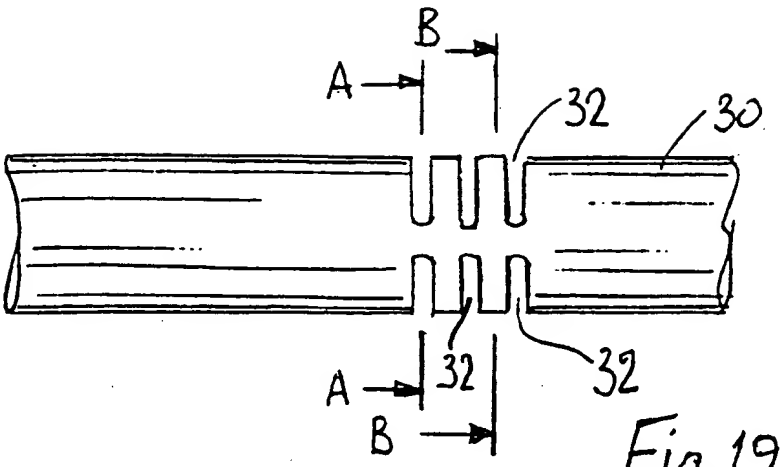

Fig. 19

A – A

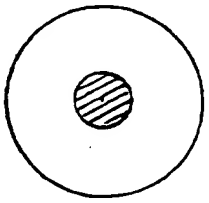

Fig. 19A

B – B

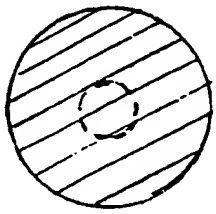

Fig. 19B

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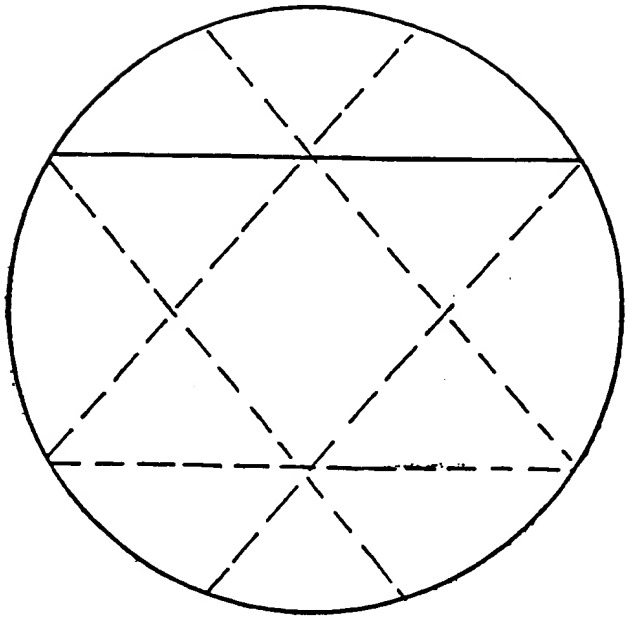

Fig. 21

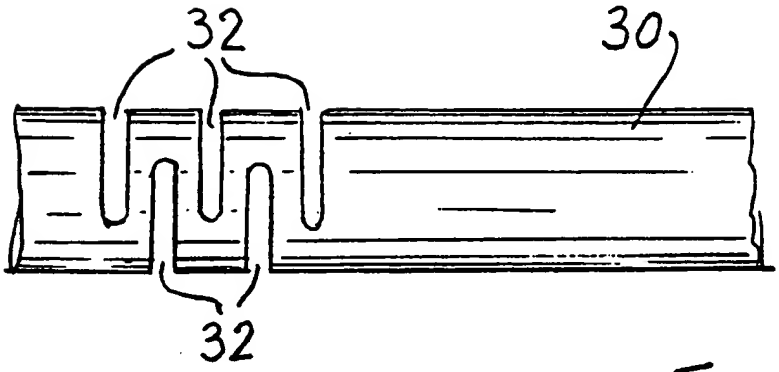

Fig. 20

INTERNATIONAL SEARCH REPORT

Int. ational Application No
PCT/IE 99/00034

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 377 453 A (BAKER SUSAN) 11 July 1990 (1990-07-11) the whole document	1-10
X	US 5 497 785 A (VIERA FERNANDO M) 12 March 1996 (1996-03-12) column 4, line 25 -column 5, line 30; figures	1-8
X	EP 0 778 039 A (SARCOS INC) 11 June 1997 (1997-06-11) column 4, line 49 -column 5, line 13; figures	1-4,6-10
X	EP 0 818 215 A (CORDIS CORP) 14 January 1998 (1998-01-14) column 3, line 20 -column 5, line 4; figures	1-3,5

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 December 1999	22/12/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 99/00034

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
A	US 4 723 549 A (WHOLEY MARK H ET AL) 9 February 1988 (1988-02-09) cited in the application column 2, line 62 -column 3, line 26; figure 1	1,11-13
E	EP 0 937 481 A (PRECISION VASCULAR SYSTEMS INC) 25 August 1999 (1999-08-25) column 4, line 2 - line 21; figures	1-4,6-10

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. ational Application No
PCT/IE 99/00034

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 5497785 A	12-03-1996	NONE	
EP 0778039 A	11-06-1997	CA 2192045 A	08-06-1997
		JP 9294813 A	18-11-1997
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		CA 2209150 A	10-01-1998
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		JP 11267224 A	05-10-1999